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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Summar	Examiner: TBD
Serial No.: 10/725,064	Group Art Unit: TBD
Filed: December 1, 2003	Title: Method for Treating Hepatic Encephalopathies
Attorney Docket No.: 02-40052-US-P	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references AA-AR and BA-CG listed in Form PTO-1449 were submitted by the Applicant in prior application Serial No. 10/122,445 filed April 12, 2002 which was claimed for priority under 35 U.S.C. § 120. The Information Disclosure Statement submitted in the earlier application complies with 37 C.F.R. § 1.98(a)-(c). Accordingly, pursuant to 37 C.F.R. § 1.98, copies of the aforementioned documents are not submitted herewith.

The above-identified Applicant submits herewith copies of references CH-CN, which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56. Form PTO-1449, attached hereto, lists references of which Applicant is aware, and which may be material to the examination of this application.

It is respectfully requested that this document be (1) fully considered during the Examination of the application; and (2) printed on any patent that may issue on the application.

While the information cited in this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. § 1.56, the filing of this reference should not be construed to be an admission that any patent, publication or other information referred to herein is, or is

considered to be, either "prior art" for this invention or otherwise material to the patentability of this invention as defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(b) exists.

This Information Disclosure Statement is being filed pursuant to 37 C.F.R. §1.97(b)(1). It is believed that no fee is due in connection with this Information Disclosure Statement, however the Commissioner is hereby authorized to charge any under payment of fees or credit any over-payment associated with this application to Deposit Account No. 18-0586.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10

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Respectfully submitted,

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SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO. 02-40052-US-P	SERIAL NO. 10/725,064
INFORMATION DISCLOSURE CITATION		
	APPLICANT: Summar	
	FILING DATE December 1, 2003	GROUP TBD

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS ***(Including Author, Title, Date, Pertinent Pages, Etc.)***

	CG	Butterworth, "Effects of Hyperammonaemia on Brain Function," J. Inher. Metab. Dis. 21 (Suppl 1) 1998; 6-20.
	CH	Lee et al., "In vivo urea cycle flux distinguishes and correlates with phenotypic severity in disorders of the urea cycle," PNAS 2000 July 5; 97(14): 8021-8026.
	CI	Way, "Portal Hypertension," Current Surgical Diagnosis & Treatment, 10th edition, Appleton & Lange; 1994: 520-536.
	CJ	Ferenci et al., "Hepatic Encephalopathy-Definition, Nomeclature, Diagnosis, and Quantification: Final Report of the Working Party at the 11th World Congresses of Gastroenterology, Vienna, 1998", Hepatology 2002; 35(3): 716-721.
	CK	Sanyal et al., "Portosystemic Encephalopathy After Transjugular Intrahepatic Portosystemic Shunt: Results of a Prospective Controlled Study," Hepatology 1994; 20(1 Pt. 1): 46-45.
	CL	Riggio et al., "Hepatic Encephalopathy After Transjugular Intrahepatic Portosystemic Shunt. Incidence and Risk Factors," Digestive Diseases and Sciences, 1996 March; 41(3): 578-584.
	CM	Thuluvath et al., "TIPS for Management of Refractory Ascites. Response and Survival Are Both Unpredictable," Digestive Diseases and Science 2003 March; 48(3): 542-550.
	CN	Groeneweg et al., "Subclinical Hepatic Encephalopathy Impairs Daily Functioning," Hepatology 1998 July; 28(1): 45-49.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	AA	4,284,647	08/18/1981	Brusilow et al.			
	AB	4,457,942	07/03/1984	Brusilow			
	AC	5,605,930	02/25/1997	Samid			
	AD	5,635,532	06/03/1997	Samid			
	AE	5,635,533	06/03/1997	Samid			
	AF	5,654,333	08/05/1997	Samid			
	AG	5,661,179	08/26/1997	Samid			
	AH	5,708,025	01/13/1998	Samid			
	AI	5,710,178	01/20/1998	Samid			
	AJ	5,712,307	01/27/1998	Samid			
	AK	5,843,994	12/01/1998	Samid			
	AL	5,852,056	12/22/1998	Samid			
	AM	5,877,213	03/02/1999	Samid			
	AN	5,883,124	03/16/1999	Samid			
	AO	5,968,979	10/19/1999	Brusilow			
	AP	6,037,376	03/14/2000	Samid			
	AQ	6,060,510	05/09/2000	Brusilow			
	AR	6,083,984	07/04/2000	Brusilow			

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OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	BA	Albrecht et al., "Hepatic Encephalopathy: Molecular Mechanisms Underlying the Clinical Syndrome," J. Neurol. Sci. 1999 Nov. 30; 170(2): 138-46.

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	BB	Albrecht, "Roles of Neuroactive Amino Acids in Ammonia Neurotoxicity," J. Neurosci. Res. 1998 Jan. 15; 51(2): 133-8.
	BC	Applegarth et al., "Incidence of Inborn Errors of Metabolism in British Columbia," 1969-1996, Pediatrics 2000 Jan.; 105(1): e10.
	BD	Batshaw, "Inborn Errors of Urea Synthesis," Ann. Neurol. 1994 Feb.; 35(2): 133-41.
	BE	Batshaw, "Hyperammonemia," Curr. Probl. Pediatr., 1984 Nov.; 14(11): 1-69.
	BF	Becker et al., "Metabolic Disease," Textbook of Neuropathology, Baltimore: Williams & Wilkins, 1997; 487.
	BG	Breningstall, "Neurologic Syndromes in Hyperammonemic Disorders," Pediatr. Neurol. 1986 Sept.-Oct.; 2(5): 253-62.
	BH	Brusilow et al., "Urea Cycle Disorders," The Metabolic and Molecular Bases of Inherited Disease, New York: McGraw-Hill, 1995; 1: 1187-1232.
	BI	Collins et al., "Neonatal Argininosuccinic Aciduira-Survival After Early Diagnosis and Dietary Management," J. Pediatr. 1980 Mar.; 96 (3 Pt. 1): 429-31.
	BJ	Del Rosario et al., "Hyperammonemic Encephalopathy After Chemotherapy. Survival After Treatment with Sodium Benzoate and Sodium Phenylacetate," J. Clin. Gastroenterol. 1997 Dec.; 25(4): 682-4.
	BK	Feillet et al., "Alternative Pathway Therapy for Urea Cycle Disorders," J. Inherit. Metab. Dis. 1998; 21 Suppl 1: 101-111.
	BL	Felipo et al., "Molecular Mechanism of Acute Ammonia Toxicity and of its Prevention by L-Carnitine," Adv. Exp. Med. Biol. 1994; 368: 65-77.
	BM	Hauser et al., "Allopurinol-Induced Orotidinuria. A Test for Mutations at the Ornithine Carbamoyltransferase Locus in Women," N. Engl. J. Med., 1990 Jun. 7; 322(23); 1641-5.
	BN	Kuntze et al., "Hyperammonemic Coma Due to Proteus Infection," J. Urol. 1985 Nov.; 134(5): 972-3.
	BO	Logan, "Neonatal Hyperammonemic Encephalopathy. Topics in Neonatal Neurology," Orlando: Grune & Stratton 1984; 137-157.
	BP	Maestri et al., "Plasma Glutamine Concentration: A Guide in the Management of Urea Cycle Disorders," J. Pediatr. 1992 Aug.; 121(2): 259-61.

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	BQ	Msall et al., "Neurologic Outcome in Children with Inborn Errors of Urea Synthesis. Outcome of Urea-Cycle Enzymopathies," N. Engl. J. Med., 1984 Jun. 7; 310(23): 1500-5.
	BR	Prasad et al., "Argininemia: A Treatable Genetic Cause of Progressive Spastic Diplegia Simulating Cerebral Palsy: Case Reports and Literature Review," J. Child. Neurol. 1997 Aug.; 12(5): 301-9.
	BS	Ratnaike et al., Hyperammonaemia and Hepatoxicity During Chronic Valproate Therapy: Enhancement by Combination with Other Antiepileptic Drugs," Br. J. Clin. Parmacol. 1986 Jul.; 22(1): 100-3.
	BT	Schaefer et al., "Dialysis in Neonates with Inborn Errors of Metabolism," Nephrol. Dial. Transplant, 1999 Apr.; 14(4): 910-8.
	BU	Schutze et al., "Hyperammonemia and Neonatal Herpes Simplex Pneumonitis," Pediatr. Infect. Dis. J., 1990 Oct.; 9(10): 749-50.
	BV	Uchino et al., "Neurodevelopmental Outcome of Long-term Therapy of Urea Cycle Disorders in Japan," J. Inherit. Metab. Dis. 21 1998; 21 Suppl 1: 151-9.
	BW	Whitington et al., "Liver Transplantation for the Treatment of Urea Cycle Disorders," J. Inherit Metab. Dis., 1998; 21 Suppl 1: 112-8.
	BX	Williams et al., "Valproic Acid-Induced Hyperammonemia in Mentally Retarded Adults," Neurology 1984 Apr.; 34(4): 550-3.
	BY	Petersdorf, et al., Harrison's Principles of Internal Medicine, 10th Edition, McGraw-Hill 1983; 125, 1775, 1781, 1814-16, 2108-09.
	BZ	Beers et al., The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, Merck Research Laboratories, 1999, 362-5, 372-6.
	CA	The Merck Manual, Sec. 4, Ch. 38, Clinical Features of Liver Disease, Portal-Systemic Encephalopathy, available at http://www.merck.com/pubs/mmanual/section4/chapter38/38f.htm, 6/23/2003.
	CB	What is a Urea Cycle Disorder?, available at http://www.nucdf.org/whatis.htm, 9/25/2003.
	CC	Hepatic Encephalopathy, available at http://members.tripod.com/enotes/hepatic-encephalopathy.htm, 6/24/2003.
	CD	Excerpt from Portal-Systemic Encephalopathy, available at http://www. emedicine.com/med/byname/portal-system-encephalopathy. htm, 6/24/2003.
	CE	Watanabe, Portal-Systemic Encephalopathy in Non-Cirrhotic Patients: Classification of Clinical Types, Diagnosis and Treatment Journal of Gastroenterology and Hepatology 15(9): 969-79, available at http://archive.mail-list.com/hbv_research/msg01824.html, 6/24/2003.

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